

FDA Commissioner's Fellowship Program
Class of 2012

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FDA Commissioner's Fellowship Program

2012 Preceptors and Fellows Projects listed by Regulatory Science Priority Area

FDA's Regulatory Science Priority Areas are articulated in the [Strategic Plan for Advancing Regulatory Science at FDA](#).

Modernize Toxicology to Enhance Product Safety

4 projects are associated with this area

Fellows and Preceptors in this area:

- Srinivasulu Chigurupati and Serguei Liachenko (NCTR)
- Narendranath Chintagari and Abdu Alayash (CBER)
- Trisha Eustaquio and Angel Paredes (NCTR)
- Javier Revollo and Vasily Dobrovolsky (NCTR)

Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

2 projects are associated with this area

Fellows and Preceptors in this area:

- Peng Duan and Lei Zhang (CDER)
- Yuzhuo Pan and Ping Zhao (CDER)

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

4 projects are associated with this area

Fellows and Preceptors in this area:

- Carmen Gacchina Johnson and Kenneth Cavanaugh, Charles Durfor, and Steven Oh (CDRH and CBER)
- Paul Keller and Ira Berkower (CBER)
- Carol Lin and Eva Rorer (CDRH)
- Carolyn Yong and Kenneth Cavanaugh, Charles Durfor, and Steven Oh (CDRH and CBER)

FDA Commissioner's Fellowship Program
2012 Preceptors and Fellows Projects listed by
Regulatory Science Priority Area

[Harness Diverse Data through Information Sciences to Improve Health Outcomes](#)

2 projects are associated with this area

Fellows and Preceptors in this area:

- Krystl Haerian and Li-Lun Chen and Wendy Aaronson (CTP)
- Yueqin Zhao and Ram Tiwari (CDER)

[Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

4 projects are associated with this area

Fellows and Preceptors in this area:

- Michael Bazaco and Debra Street (CFSAN)
- Kirsten Hirneisen and Donna Williams-Hill (ORA)
- Anita Khatiwara and Thomas Hammack (CFSAN)
- Niharika Mishra and John Larkin (CFSAN)

[Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security](#)

2 projects are associated with this area

Fellows and Preceptors in this area:

- Bernard Marasa and Saeed Khan (NCTR)
- Justina Tam and Charles Clavet (ORA)

FDA Commissioner's Fellowship Program

2012 Preceptors and Fellows by Center

CBER

Preceptor

Abdu Alayash
Ira Berkower
Kenneth J. Cavanaugh,
Charles Durfor, and
Steven Oh

Fellow

Narendranath R. Chintagari
Paul Keller
Carolyn Yong

CDER

Preceptor

Lei Zhang
Ping Zhao
Ram Tiwari

Fellow

Peng Duan
Yuzhuo Pan
Yueqin Zhao

CDRH

Preceptor

Kenneth J. Cavanaugh,
Charles Durfor, and
Steven Oh
Eva M. Rorer

Fellow

Carmen Gacchina Johnson

Carol Lin

CFSAN

Preceptor

Debra A. Street
Thomas S. Hammack
John W. Larkin

Fellow

Michael Bazaco
Anita Khatiwara
Niharika Mishra

FDA Commissioner's Fellowship Program

2012 Preceptors and Fellows by Center

CTP

Preceptor

Ii-Lun Chen and
Wendy Aaronson

Fellow

Krystl Haerian

NCTR

Preceptor

Serguei Liachenko
Angel Paredes
Saeed Khan
Vasily Dobrovolsky

Fellow

Srinu Chigurupati
Trisha Eustaquio
Bernard Marasa
Javier Revollo

ORA

Preceptor

Donna M. Williams-Hill
Charles R. Clavet

Fellow

Kirsten Hirneisen
Justina Tam

FDA Commissioner's Fellowship Program
2012 Fellows



Michael C. Bazaco, Ph.D., M.S.

Center for Food Safety and Applied Nutrition (CFSAN)
Office of Analytics and Outreach (OAO)

Preceptor: Debra Street, Ph.D., M.P.H.

Scientific and Professional Background

Ph.D.	Epidemiology	University of Pittsburgh	2012
M.S.	Food Science and Technology	Virginia Tech	2004
B.S.	Biology	Virginia Tech	2001
	Biology	University of South Carolina	

Research Interests

Michael's research interests focus mainly on the epidemiology of foodborne illness and its application to food safety. He has worked on the optimization of environmental sampling techniques for pathogens. In addition, he has assessed pathogen ecology in processing plants while completing his MS at Virginia Tech. His doctoral research focused on social epidemiology. Specifically, he developed a reliable instrument to measure neighborhood contentedness in adolescents using statistical inference. In addition, he looked at the association between this measure and physical activity and screen time in adolescents. He also worked on statistical development of a trajectory analysis model for traumatic brain injury treatment and evaluation, as well as infectious disease epidemiology projects concerning nosocomial infections and vaccine coverage. He also acted as the teaching fellow for three years and was involved with the development and execution of various graduate level epidemiology courses. Public health communication and learning is also a major interest of his.

Commissioner's Fellowship Project Overview

Temporal Trends in Outbreak Attribution of Produce and Juices Compared to Other Food Groups

FDA Regulatory Science Priority Area: [Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

Michael will be looking at temporal trends in the attribution of food borne diseases in various commodity/pathogen combinations.



Srinu Chigurupati, D.V.M., Ph.D.

National Center for Toxicological Research (NCTR)

Preceptor: Serguei Liachenko M.D., Ph.D .

Scientific and Professional Background

2010-2012	Research Scientist: National Institute on Aging, NIH, Baltimore, MD & College of Medicine, University of Central Florida, Orlando FL
2008-2010	Research Scientist: College of Medicine, University of Central Florida, Orlando FL
2005-2008	Postdoctoral Visiting Fellow, National Institute on Aging, NIH, Baltimore, MD
1997	PhD, College of Veterinary Science, Rajendranagar, AP, India
1991	MVSc, College of Veterinary Science, Tirupati, AP, India
1987	DVM, College of Veterinary Science, Tirupati, AP, India

Licenses and Certification: He is licensed by AVMA to practice Veterinary Medicine in USA; He is also certified by NIH in Clinical Pharmacology and Clinical Trials.

Research Interests

His research interests are broadly in studying the mechanisms involved in neuronal damage, related to aging and chronic neurodegenerative diseases such as Alzheimer's, Parkinson's and ALS. Also, studying molecular basis of glioblastomas to identify novel drug targets and developing new animal study protocols in Neuro-Oncology and Neuroscience. He is looking forward to learn more about regulatory science in the Commissioner's fellowship program to protect & promote the public health and expand skill set in identification of novel neurotoxicity biomarkers through Magnetic Resonance Imaging (MRI) and Magnetic Resonance Spectroscopy (MRS).

Commissioner's Fellowship Project Overview

Confirmative Neuropathology studies with MRI Imaging and Informatics

FDA Regulatory Science Priority Area: [Modernize Toxicology to Enhance Product Safety](#)

Development of MRI/MRS biomarkers of neurotoxicity in laboratory animals. Prototypic neurotoxic compounds will be used to induce brain lesions with the intent of identifying associated metabolic changes in affected tissue. Evaluation of quantitative imaging (MRI/MRS, positron emission tomography) for identifying new potentially translational biomarkers and predictors of safety and efficacy.



**Narendranath Chintagari, BVSc & AH (DVM),
MVSc, Ph.D.**

Center for Biologics Evaluation and Research (CBER)

Preceptor: Abdu I. Alayash, Ph.D.

Scientific and Professional Background

2010	Postdoctoral Associate; Yale University
2008-09	Postdoctoral fellow and Research Associate; Oklahoma State University
2007	PhD (Veterinary Biomedical Sciences); Oklahoma State University
2002	M.V.Sc (Pharmacology); Anand Agricultural University
1999	B.V.Sc & A.H, Sri Venkateshwara Veterinary University

Research Interests

Dr. Chintagari's research interests mainly focused on understanding the pathophysiology of lung functioning. His doctoral research unraveled the role of lung lipid rafts in surfactant secretion. He also studied multiple acute lung injury diseases such as Acute Respiratory Distress Syndrome (ARDS), Ventilator-induced lung injury (VILI) and hyperoxia-mediated lung injury. His other interests include fetal lung development and its anomalies such as Congenital Diaphragmatic Hernia (CDH), Bronchopulmonary Dysplasia (BPD). Recently, he investigated the therapeutic efficacy of Transient Receptor Protein (TRP) receptors in ameliorating irritant-induced skin injury in mice. His current research will investigate hemoglobin-based oxygen carriers (HBOC)-induced lung injury. The present studies might reveal mechanisms to mitigate their pulmonary toxicity.

Commissioner's Fellowship Project Overview

Investigation of Hemoglobin-induced pulmonary toxicity

FDA Regulatory Science Priority Area: [Modernize Toxicology to Enhance Product Safety](#)

Blood transfusion is a commonly used critical lifesaving procedure in intensive care units. Massive transfusion and red blood cell lysis in sickle cell disease and thalassemia releases hemoglobin into the vasculature. Excessive amounts of cell free hemoglobin are injurious to multiple tissues.

Lungs are one of the highly perfused tissues. They are potentially exposed to high concentrations of acellular hemoglobin not only in hemolytic diseases but also during acute lung injury. The presence of excess acellular hemoglobin might affect lung functioning. The present study is hence designed to study the toxicity of hemoglobin on lung epithelial cells *in vitro* and *in vivo*. Understanding the mechanisms of hemoglobin-induced epithelial injury might enable us to devise strategies to minimize the pulmonary injury. Our study might also provide valuable input in developing hemoglobin based oxygen carriers which are safe and effective.



Peng (Vincent) Duan, Ph.D.

Center for Drug Evaluation and Research (CDER)
Office of Translational Sciences (OTS)
Office of Clinical Pharmacology (OCP)

Preceptor: Lei Zhang, Ph.D.

Scientific and Professional Background

1994-1998 B.S. in Pharmaceutical Science
2001-2007 Ph.D. in Neuroscience
2007-2012 Research Assistant Professor

China Pharmaceutical University
State University of New York at Buffalo
Rutgers, State university of New Jersey

Research Interests

Dr. Duan's research areas include drug transporter functional regulation and transporter associated drug-drug interactions (DDIs) studies. He is interested in utilizing the current knowledge and understanding of transporter functions and regulation mechanisms to investigate and predict clinical DDIs to assist regulatory review and the development of regulatory guidance. Dr. Duan has extensive experience in molecular biology, neuroscience, and pharmaceutical sciences.

Commissioner's Fellowship Project Overview

Construction of a Drug Transporter Database and Utilization of the Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulation to Predict and Analyze Transporter-mediated Drug-drug Interactions (DDIs)

FDA Regulatory Science Priority Area: [Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes](#)

Transporter-Mediated DDIs, caused by competition of the same transporter pathways among co-administrated drugs, can lead to significant changes in the safety or efficacy profiles of the affected drug. Therefore, assessing the clinical relevance of transporter-mediated drug interactions has become an integral part of risk assessments during drug development and regulatory approval processes. A database containing transporter information from NDA/IND submissions will be a very helpful resource to reviewers. FDA's 2012 draft guidance on drug interactions has recommended the application of modeling and simulation in the prediction of DDI risk. In this project, a transporter database mainly based on the information from NDA/IND submissions will be constructed. In addition, a best practice document on in vitro transporter assays will be to help improve quality of in vitro transporter studies and aid transporter study review. Finally, mechanistic static models as well as dynamic PBPK models will be constructed to evaluate DDI risk associated with statin drugs that involve several transporters and metabolizing enzymes.



Trisha Eustaquio, Ph.D.

National Center for Toxicological Research (NCTR)

Preceptor: Angel M. Paredes, Ph.D.

Scientific and Professional Background

2007-2012	Ph.D. Biomedical Engineering, Purdue University, West Lafayette, IN
2011	Consultant, Nanovis, West Lafayette, IN
2009	Summer Intern, Dow AgroSciences, Indianapolis, IN
2005-2007	Research Associate, Cytellect, San Diego, CA
2003-2005	Research Associate, Acidophil, San Diego, CA
2000-2004	B.S. Bioengineering with minor in Mathematics, University of California, San Diego, La Jolla, CA

Research Interests

- Engineering nanomedical devices
- Nanotoxicology and the environmental impact of nanotechnology
- Development of methodologies for the physicochemical and biological characterization of novel nanomaterials
- Scientific and regulatory issues of nanomaterial-based products
- Nanotechnology education
- Development of 3D electron microscopy techniques for toxicological research

Commissioner's Fellowship Project Overview

Assessment of mitochondrial ultrastructure and function after ketamine treatment in the developing rat brain

FDA Regulatory Science Priority Area: [Modernize Toxicology to Enhance Product Safety](#)

Ketamine, an FDA-approved N-methyl-D-aspartate (NMDA) receptor antagonist, is commonly used for general pediatric anesthesia. Accumulating evidence indicates that continuous exposure to ketamine induces extensive neuronal cell death in the developing brains of experimental animals. Little is known, however, about the overall changes in the mitochondrial ultrastructure that may accompany the distinct events in this cell death process. Thus, 2D and 3D methods of electron microscopy (EM) will be utilized to examine alterations in the mitochondria ultrastructure after ketamine treatment and then correlate them to mitochondrial (dys)function in the rodent model. This project will allow the development of new EM techniques that may provide critical information for first detecting and then understanding the relative risks associated with the use of ketamine and the subsequent impact on regulation of similar anesthetic agents. Such powerful EM methodologies can also be used in a variety of FDA studies, in which structure plays a critical role in studying drug or nanomaterial interactions.



Carmen Gacchina Johnson, Ph.D.

Regenerative Medicine Project
Center for Devices and Radiological Health (CDRH)
Center for Biologics Evaluation and Research (CBER)

Preceptors: Kenneth J. Cavanaugh Jr., Ph.D. (CDRH), Charles Durfor, Ph.D. (CDRH), and Steven S. Oh, Ph.D. (CBER)

Scientific and Professional Background

2010-2012 Imaging Science Training Postdoctoral Fellow
National Institutes of Health (NIH), Bethesda, MD
2010 Ph.D. Bioengineering
Clemson University, Clemson, SC
2006 B.S. Materials Science and Engineering
Michigan State University, East Lansing, MI

Research Interests

Carmen's research interests are cardiovascular regenerative medicine, intravascular image-guided therapies, and local drug delivery. Her graduate research focused on regenerative medicine for treatment of extracellular matrix degradation from vascular disease. She utilized animal models that recapitulated varying stages of clinical abdominal aortic aneurysms (AAA), and then therapeutically delivered biomolecular agents to the derived cells. These biomolecules stimulated extracellular elastic matrix repair with significant success. The challenges of sustained delivery of such therapeutic agents to a target pathologic location, such as the site of AAA, sparked her interest in local drug delivery. Therefore, she pursued an opportunity to expand her expertise into the field of image-guided therapies and local drug delivery for her postdoctoral training. Carmen's postdoctoral research projects included image-guided local embolic and drug delivery for liver cancer therapy, low temperature sensitive liposome (LTSL) drug delivery and high intensity focused ultrasound (HIFU) for enhanced thrombolysis, MR-guided HIFU for targeted drug delivery of LTSLs in a tumor model, and a minimally-invasive large animal model of AAA for testing endovascular therapeutic devices. In all of these projects, she focused on understanding the biologic response to local therapy.

Commissioner's Fellowship Project Overview

Opportunities and challenges in applying existing biocompatibility standards for the safety evaluation of cardiovascular device-biologic combination products

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

Standard approaches for evaluating the biologic safety of a product may not be appropriate or sufficiently informative for device-biologic combination products. For this project, Carmen will address the following issues for cardiovascular device-biologic products:

- 1) When the current methods of evaluating biocompatibility provide meaningful and sufficient data
- 2) What criteria should be met so that meaningful and sufficient biocompatibility/preclinical data can be based on published literature of similar products
- 3) Under what conditions and how sample preparation methods should be modified to provide more accurate evaluation of biocompatibility (e.g., studies on components rather than a final product)
- 4) Under what conditions additional / new tests should be considered to augment the current bio-material biocompatibility test methods

Carmen will review the data available for investigational and approved products with the ultimate goal of suggesting updated biocompatibility testing guidelines for cardiovascular device-biologic combination products.



Krystl Haerian, M.D.

Center for Tobacco Products (CTP)
Office of Science (OS)

Preceptors: Li-Lun Chen, M.D. and
Wendy Aaronson

Scientific and Professional Background

2009-2012 Columbia University, Department of Biomedical Informatics,
NLM funded graduate student (M.S., Biomedical Informatics)
2009 U.S. House of Representatives, Office of Hon. Lucille Roybal-Allard,
WREI Congressional Fellow
2008 National Institute of Health, Clinical Center,
Laboratory for Informatics Development, Postdoctoral Fellow
Education: M.D., University of Maryland School of Medicine;
M.S., Biotechnology, Johns Hopkins University;
B.S., Biological Sciences, UMBC

Research Interests

Dr. Haerian's research prior to joining the FDA was focused on the secondary use of Electronic Health Record data for the detection of pharmacovigilance and drug repurposing signals. Her research included methods to improve capture of clinical research data, automated phenotype extraction, and methods to reduce noise and confounding in big data sets. At the FDA, her hope is to translate fundamental clinical and informatics knowledge and methods to organize, structure, and label documents germane and relevant for specific clinical themes for rapid review and evaluation by CTP scientists.

Commissioner's Fellowship Project Overview

Streamlining Tobacco Industry Submissions to the FDA Center for Tobacco Products

FDA Regulatory Science Priority Area: [Harness Diverse Data through Information Sciences to Improve Health Outcomes](#)

The fellowship project has two main components, the first is to develop a draft guidance for standardized electronic submissions to CTP and the second is to utilize data mining techniques to study confidential health documents submitted to CTP under the Tobacco Control Act. Current standards, such as the eCTD and CDISC, that are in use at other FDA centers for electronic submissions will be evaluated for potential utility at CTP. The fellow will plan a workshop on electronic submission standards for industry and interested parties. Research work will include applying preprocessing and data-mining techniques to explore a large corpus of confidential industry documents to identify collections of documents and studies relevant to scientific reviewers. The fellow will also participate in the clinical review of investigational tobacco product applications.



Kirsten Hirneisen, Ph.D.

Office of Regulatory Affairs (ORA)

Preceptor: Donna Williams-Hill, Ph.D.

Scientific and Professional Background

2008-2012 Ph.D. Food Microbiology, University of Delaware, Newark, DE

2006-2008 M.S. Food Science, University of Delaware, Newark, DE

2002-2006 B.S. Biochemistry/Cell Biology, Bucknell University, Lewisburg, PA

Research Interests

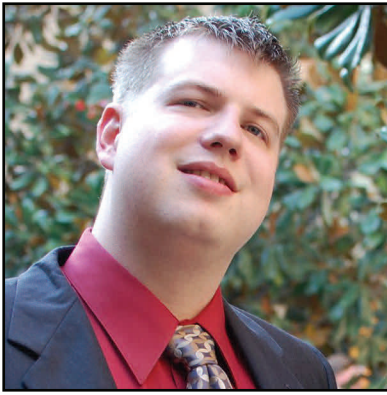
Kirsten's research interests encompass a variety of topics in the field of microbial food safety. Her graduate research focused on the interaction of enteric viral pathogens with fresh produce in the pre-harvest environment as well as post-harvest processing treatments. Current research projects as a Commissioner's Fellows will focus on development and validation of methods testing for pathogens in food matrices.

Commissioner's Fellowship Project Overview

Developing a Universal Enrichment Broth for Foodborne Bacterial Pathogens

FDA Regulatory Science Priority Area: [Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

Successful prevention of foodborne illness requires the development of rapid and reliable pathogen detection methods for testing of foods. Depending on the food matrix and target pathogen, different pre-enrichment broths are used when following the Bacteriological Analytical Manual (BAM) for sample preparation prior to conventional culturing of foodborne bacterial pathogens. The preparation of multiple pre-enrichment broths is labor intensive, time consuming and costly, and the need to use multiple enrichment broths is a major roadblock when trying to develop rapid methods designed for multi-target pathogen detection such as multiplex qPCR. The objective of this research project is to develop a universal enrichment broth to simultaneously propagate multiple foodborne bacterial pathogens including Gram negative and Gram positive pathogens in food matrices. A universal enrichment broth combined with multiplex qPCR detection will reduce media requirements and sample analysis time in addition to resulting in a high-throughput, streamlined approach. This method will increase the capacity of detecting multiple pathogens which is critical to the rapid detection of pathogens in food samples by public health laboratories.



Paul W. Keller, Ph.D.

Center for Biologics Evaluation and Research (CBER)
Division of Viral Products, Office of Vaccines

Preceptor: Ira Berkower, M.D., Ph.D.

Scientific and Professional Background

- Postdoctoral Fellowship: 2007-2012; Laboratory of Structural Biology Research, NIAMS/NIH
- Cornell University, 2007: Ph.D., Genetics & Development
- Carnegie Mellon University, 2001: B.S., Biological Sciences

Research Interests

Dr. Keller's primary research interest is the study of viruses and other infectious human pathogens, with a particular emphasis on retroviruses such as HIV-1. For his doctoral research, Dr. Keller studied the assembly pathway of retroviruses using molecular biology, genetic, and imaging techniques. In his postdoctoral work at NIH, Dr. Keller focused on investigating retroviral maturation and its inhibition using three-dimensional electron microscopy techniques. As an FDA Commissioner's Fellow, Dr. Keller looks forward to applying his molecular and structural biology experience to the design of potential HIV-1 vaccine antigens and effective delivery vectors.

Commissioner's Fellowship Project Overview

Designing HIV-1 Vaccine Immunogens by Stabilizing gp120 with an Exposed CD4 Receptor Binding Site

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

More than 30 years after the first description of the disease, HIV/AIDS remains a global health pandemic. Despite decades of research, there is no effective vaccine against HIV infection, or cure for those already infected with the virus. The surface glycoprotein of HIV-1, Env (gp120), utilizes several strategies to evade effective immune recognition, including structural plasticity, sequence variability, and epitope shielding. Nevertheless, gp120 is the target of most known broadly neutralizing antibodies (nAbs) against the virus due to its critical role in virus binding and entry to host cells. The goal of this project is to use structural biology-guided mutagenesis to investigate the design of HIV-1 vaccine immunogens based on gp120. By engineering a stabilized minimal gp120 construct that retains the CD4 receptor binding site (CD4bs) activity but eliminates structural plasticity and shielding, we strive to create an antigen that avoids Env's natural defense mechanisms, is highly immunogenic, and is able to elicit nAbs against primary HIV-1 isolates. In addition, we are developing novel forms of gp120 that are small enough for expression in a live viral vector, yet retain the CD4bs target for nAbs. This work will contribute to the FDA's knowledge of effective vaccine antigen design, as well as provide insight to assist in regulatory review of potential vaccine candidates.



Anita Khatiwara, Ph.D.

Center for Food Safety and Applied Nutrition (CFSAN)

Preceptors: Thomas Hammack, M.S.

Scientific and Professional Background

2007-2012	Ph.D., Cell and Molecular Biology, University of Arkansas, Fayetteville, AR
2005-2007	M.S., Cell and Molecular Biology, University of Arkansas, Fayetteville, AR
2001-2005	Veterinary Practitioner, Gangtok, Sikkim, India
1996-2001	B.V.Sc. & A.H., (≈ DVM) Bachelor of Veterinary Sciences and Animal Husbandry, Acharya N.G. Ranga Agricultural University, Hyderabad, India

Research Interests

Dr. Khatiwara's research interests lie in the fields of Microbiology, Molecular Biology, Food Safety, and Public Health. Her doctoral research focused on functional genomics of *Salmonella* Typhimurium to identify conditionally essential genes. These genes could be an important resource for better understanding the ability of bacteria to survive/persist in various environments including food matrices and food contact surfaces. The knowledge gained could assist in developing strategies to prevent bacterial contamination of food. Her research interests at FDA are to build up on her academic and research experience and apply various microbiological and molecular biological techniques for the development of improved methods of detection of food-borne pathogens. She believes the laboratory research experience along with regulatory experience she expects to gain here at FDA will impart the skills/knowledge that is essential to work for the betterment and safeguarding of human health.

Commissioner's Fellowship Project Overview

*Development and validation of an environmental testing method for the detection of *L. monocytogenes* in food processing environment*

FDA Regulatory Science Priority Area: [Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

Effective environmental testing procedures are critical for identifying source of contamination during an outbreak. Recently *L. monocytogenes* has been implicated in a major multi-state outbreak associated with contaminated cantaloupes and it is the deadliest foodborne outbreak in more than a decade. The investigation of this outbreak identified the processing environment as a source of contamination. The current FDA Bacteriological Analytical Manual (BAM) contains analytical methods for the detection of *L. monocytogenes* in various food matrices. However, there are no validated methods for environment testing of the pathogens by FDA. Her research project will focus on the development and validation of testing procedures including sample collection, handling, enrichment, screening, isolation and confirmation of *L. monocytogenes* in food processing environment, especially food contact surfaces. The environmental testing and monitoring protocols for the pathogen will guide industry to develop effective sanitation procedures to ensure safety of final food products.



Carol Lin, M.D.

Center: Center for Devices and Radiological Health (CDRH)

Preceptor: Eva Rorer, M.D.

Scientific and Professional Background

2010 – 2011 Attending ophthalmologist, Queens-Long Island Medical Group, P.C.
2009 – 2010 Fellowship in glaucoma, Mt. Sinai Medical Center, New York
2006 – 2009 Residency in ophthalmology, New York Medical College-St. Vincent Catholic
Medical Center, Manhattan
2005 – 2006 Internship in medicine, University of Maryland Medical Center
2005 M.D., University of Maryland School of Medicine
2000 B.A. in biology, Washington University

Research Interests

Technological innovation in ophthalmological therapeutics has been emerging at a rapid pace over recent years, with ongoing regulatory and economic implications. Drawing upon my previous clinical experiences as a comprehensive ophthalmologist and glaucoma specialist, I would like to explore the reciprocating effects between these innovation trends, federal regulation and public health while learning about the premarket regulatory processes for ophthalmic device submissions.

Commissioner's Fellowship Project Overview

Development of a Guidance Document for Ophthalmic Optical Coherence Tomography Imaging Devices

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

The rapid pace of developments in diagnostic ophthalmic imaging technology over the past several years has been accompanied by an increase in related marketing submissions, particularly for devices employing optical coherence tomography (OCT) technology. However, appropriate endpoints and strategies for the assessment of new ophthalmic OCT device functions and claims remain unclear. Even as these OCT devices assert increasing importance to clinicians, no guidance exists for FDA staff or industry on how to evaluate advances in ophthalmic OCT technology and related labeling claims. A recent workshop jointly sponsored by the FDA and the American Glaucoma Society invited stakeholders (clinicians, academicians, and industry) to discuss regulatory science aspects of and strategies for characterizing and assessing the performance of OCT devices used for the diagnosis and management of glaucoma. The objectives of this project are to utilize the feedback obtained from the workshop and to incorporate it into a guidance document for industry and staff to improve the quality and consistency of pre-market submissions for ophthalmic OCT devices. As a regulatory agency, the FDA is responsible for advancing public health by facilitating the development of product innovations and the public's access to accurate, science-based information necessary for appropriate use of medical devices. One of the ways to meet these regulatory goals is to promote consistency in the path to product clearance while maintaining clear scientific standards of product validation, reliability, and usability. Progress towards a published guidance document will contribute to the FDA's overall public health mission.



Bernard S Marasa, Ph.D.

National Center for Toxicological Research (NCTR)
Division of Microbiology

Preceptor: Saeed A Khan, Ph.D

Scientific and Professional Background

2010-2012	Research Associate, HIV-1 Vaccine, The Catholic Univ. of America (CUA), Washington DC
2007-2010	Post-Doctoral Associate, Laboratory of Cellular & Molecular Immunology, NIA-IRP; National Institute of Health, Baltimore, MD
2003-2007	Ph.D. Molecular Pathology, University of Maryland Baltimore, MD
2001-2003	Research Associate, Dept of Surgery, University of Maryland, Baltimore, MD
1999-2001	M.Sc. Mol. Biology, Vrije Universiteit Brussel, Belgium
1997-1999	Research Assistant, International Livestock Research Institute (ILRI), Nairobi, Kenya
1993-1997	B.Sc. (Biochemistry) JKUAT, Nairobi, Kenya

Research Interests

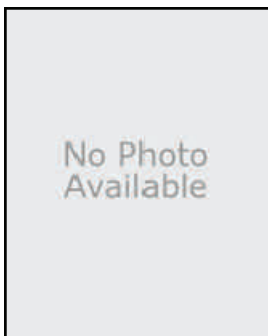
Dr. Marasa's research interests are primarily in cellular signaling, gene expression profiling, siRNA/microRNA gene therapy and characterization of disease biomarkers. He is also interested in learning about FDA's regulatory science and policies especially in relation to toxicological evaluation of biologics, drugs and gene therapy products. His current research is focused on the analysis of global cellular gene expression and microRNA profiling on the pulmonary, cutaneous and Intestinal primary cells upon infection with avirulent anthrax strain *Bacillus anthracis*. His Ph.D. research focused on cloning and characterizing TRPC calcium ion channels and downstream cellular signaling pathways in intestinal epithelial cells. In his post-doctoral training at the NIA-NIH, his research focused primarily on role of RNA Binding Proteins (RBPs) and microRNAs in post-transcriptional gene regulation during cellular senescence. At CUA, he was mainly involved in designing a novel HIV-1 ENV gene immunogen and engineering bacteriophage T4 capsids for use as a potential HIV-1 vaccine platform.

Commissioner's Fellowship Project Overview

*Gene expression profiling in pulmonary, gastrointestinal and cutaneous epithelial cell lines after infection with *Bacillus anthracis* Sterne*

FDA Regulatory Science Priority Area: [Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security](#)

Anthrax disease manifests itself in three forms, which differ in severity; however the cause of the differences in severity and disease outcome is poorly understood. The outcome of the disease is probably dependent upon the interaction of anthrax toxins with cellular targets at the site of infection. To fully understand causes of severity differences among the three forms of anthrax disease manifestations; we seek to study the whole gene expression profile of the pathogen; *B. anthracis* and host cells to identify key intracellular signaling and pro-inflammatory response pathways involved in each form of the disease. Evaluation of these downstream signaling pathways may lead to identification of new potentially translational biomarkers of anthrax disease which FDA can utilize for the expeditious development and licensing of products to diagnose, treat or prevent anthrax following exposure.



Niharika Mishra, Ph.D.

Center for Food Safety & Applied Nutrition (CFSAN)

Preceptor: John Larkin, Ph.D.

Scientific and Professional Background

2011-2012	Postdoctoral associate, The Pennsylvania State University
2011	Ph.D. Agricultural & Biological Engineering, The Pennsylvania State University
2003	M.Tech. Dairy and Food Engineering, Indian Institute of Technology, Kharagpur, India
2000	B.Tech. Agricultural Engineering, Orissa University of Agriculture & Technology (OUAT), Bhubaneswar, India.

Research Interests

My research interest is in the area of food process engineering, primarily focused on process establishment and validation. I am interested in studying inactivation of pathogenic microorganisms in food by various emerging technologies and development of mathematical models for risk analysis. During my PhD. I worked on development of predictive models for inactivation, injury and recovery of foodborne pathogen in UHT whole milk following high pressure and temperature treatment. My M.Tech project work involved, design and development of an aseptic packaging machine for sterilized milk.

Commissioner's Fellowship Project Overview

Validation of Extrusion Processing for Inactivation of Salmonella in Low Moisture Model Foods

FDA Regulatory Science Priority Area: [Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

During the past several decades, numerous outbreaks of salmonellosis have been linked to low moisture foods such as peanut butter, tree nuts, dry seasoning, powered infant formula, cereal, and pet food. Among these outbreaks many are associated with extruded food products such as cereals, snack foods and pet foods. Thus, an urgent need exists for minimization of microbial safety hazards in extruded food products. Eradication of *Salmonella* by thermal treatment is difficult due to the high thermal resistance of *Salmonella* at low moisture content or water activity (a_w). Moreover, the reported extrusion studies describing microbial inactivation lack comprehensive data in varying moisture content and temperature. Our goal is to evaluate the efficacy of extrusion as an inactivation step for *Salmonella* in different foods over a range of moisture and temperature. The main objectives of the research are 1) Identify the most resistant *Salmonella* strain from a diverse collection of food, clinical and environmental isolates associated with low moisture foods and related outbreaks; 2) Determine the microbial inactivation kinetics of *Salmonella* (most resistant strain obtained from objective 1) in low moisture food matrices of varying moisture content and the composition of starch, protein and fat content. 3) Study the microbial inactivation efficacy of a pilot-scale extruder over a range of moisture and temperature and predict the minimum process conditions to achieve a target reduction of *Salmonella* by developing and validating a statistical model.



Yuzhuo Pan, Ph.D.

Center for Drug Evaluation and Research (CDER)
Office of Translational Sciences
Office of Clinical Pharmacology

Preceptor: Ping Zhao, Ph.D.

Scientific and Professional Background

2008-2012 Postdoctoral Research Associate, Pharmaceutical Sciences, State University of New York at Buffalo, NY
2006-2008 Visiting Scholar, Urology, Tohoku University Hospital, Japan
2002-2007 Ph.D. Pathology & Pharmacology, Jilin University, China
1997-2002 M.D. Medicine, Norman Bethune College of Medicine, Jilin University, China

Research Interests

- Population-based, physiologically-based pharmacokinetic (PBPK) modeling.
- Drug metabolizing enzymes, transporters and drug drug interaction.
- Pharmacokinetics and pharmacodynamics modeling and simulation.

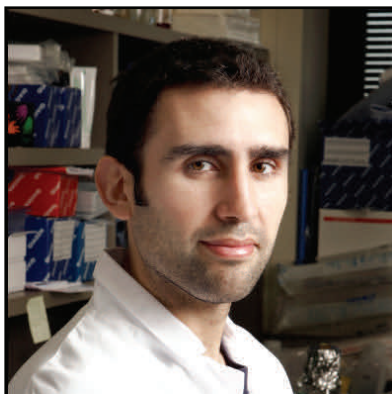
Through my educational and professional training, I have acquired in-depth knowledge in preclinical and clinical pharmacokinetics and pharmacodynamics. My current research interests involve the best practice of physiologically based pharmacokinetic models in drug development and regulation.

Commissioner's Fellowship Project Overview

Establishing A Knowledge-base of Physiologically-based Pharmacokinetic (PBPK) Models to Support Regulatory Review

FDA Regulatory Science Priority Area: [Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes](#)

Physiologically-based pharmacokinetic (PBPK) model is an effective tool during different stages of drug development by facilitating decision making. By integrating drug-dependent and system (physiology)-dependent information, PBPK model can help us understand the interaction between drug molecule and the physiological system through a "predict-learn-confirm" cycle. Recently, drug industries have adopted PBPK models to support their IND/NDA submissions. My project is to establish a PBPK model knowledge base by summarizing experience gained in recent review/research in the Office of Clinical Pharmacology. The extensive information accumulated in the knowledge base will improve our understanding of physiology and drug behavior, which in turn contributes scientific field. The established knowledge-base is expected to have significant impact on regulatory review.



Javier Revollo, Ph.D.

National Center for Toxicological Research (NCTR)

Preceptor: Vasily Dobrovolsky, Ph.D.

Scientific and Professional Background

- 2011-2012 Scientist, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC.
- 2006-2011 IRTA Fellow, National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC.
- 2001-2006 PhD in Molecular Cell Biology, Washington University in St. Louis, MO.
- 1997-2000 BS in Genetics, University of Wisconsin-Madison, WI.

Research Interests

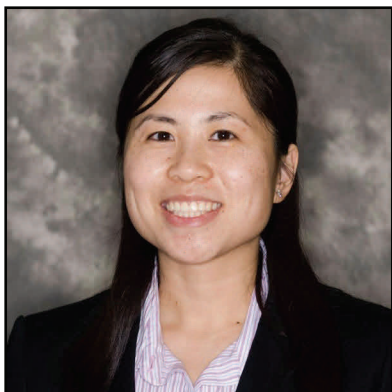
Dr. Revollo's interests involve the study of genomic and transcriptional changes elicited by environmental stimuli. In the recent past—through next generation sequencing techniques—he has studied how nuclear receptors alter the transcriptional landscape (exome) of cells and tissues. He is now applying these technologies and developing new ones to study how toxic compounds affect the exome as well as the genetic stability of cells.

Commissioner's Fellowship Project Overview

Characterization of the TK9 Exome by 454 Next Generation Sequencing

FDA Regulatory Science Priority Area: [Modernize Toxicology to Enhance Product Safety](#)

Next generation sequencing (NGS) refers to a number of technologies that have made sequencing of nucleic acids fast and affordable. While they are commonly used to sequence entire genomes, NGS can also be directed to study a subset of genetic material, such as exomes, or the areas of the genome that encode proteins and non-coding RNAs. Dr. Revollo is employing NGS to find, catalogue, and characterize mutations created by exposure to toxins and localized in the exomes of cell lines commonly used for toxicological assays (e.g., TK6). His findings would inform regulatory agencies about the reliability of these cells for toxicological assays and establish a new technique to assess toxicity in a genome-wide scale.



Justina Tam, Ph.D.

Office of Regulatory Affairs (ORA)

Preceptor: Charles Clavet, Ph.D.

Scientific and Professional Background

The University of Arizona: B.S. in Biosystems Engineering, 2002-2006

The University of Texas at Austin: Ph.D. in Biomedical Engineering, 2006-2012

Research Interests

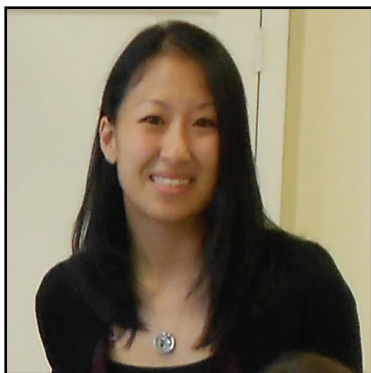
Justina's research interests focus on detecting pathogens using molecular-specific contrast agents. Traditional methods of detecting pathogens in the body involve using radioactive and fluorescent labels, but radioactive imaging is dose-limiting and fluorescent imaging is limited in optical stability. To make these imaging methods more efficient, metal nanoparticles can be used as robust molecular markers because they are biocompatible and optically stable. Justina's research experience has focused on using gold nanoparticles to detect both cancer *in vivo* and viral protein markers *ex vivo*.

Commissioner's Fellowship Project Overview

Rapid Detection of Pathogens using Nanoparticles functionalized with Aptamers, with Real-time Analysis

FDA Regulatory Science Priority Area: [Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security](#)

A major challenge in countering an outbreak, whether from a contaminated food supply or from a bioterror attack, is a lack of a method to provide population-based rapid diagnostics and real-time monitoring. One step to overcoming this challenge is to use a point-of-care (POC) device, which is a mobile device that can rapidly detect pathogens. Current POC devices, however, do not allow for real-time monitoring, and typically detect only a single pathogen. Justina's project aims to detect viruses and food pathogens by developing a multiplexed lateral flow-based POC device that will be used with a mobile phone application to allow for real-time epidemiology analysis.



Carolyn Yong, Ph.D.

Multi-Center Fellowship in Regenerative Medicine
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

Preceptors: Kenneth J. Cavanaugh Jr., Ph.D. (CDRH), Charles Durfor, Ph.D. (CDRH), and Steven S. Oh, Ph.D. (CBER)

Scientific and Professional Background

- 2011 Ph.D. Bioengineering & Biotechnology,
École Polytechnique Fédérale de Lausanne (EPFL)
- 2000 M.S.E. Chemical Engineering, Johns Hopkins University
- 1998 B.S.E. Biomedical Engineering and B.S.E. Chemical Engineering,
Johns Hopkins University

Research Interests

Dr. Yong's research background lies in lymphatic biology, tissue engineering, interstitial fluid and tissue mechanics, and surface science. Her doctoral research aimed to characterize the lymphatic endothelium, in particular, its functional-adaptive response to biologics (VEGF-C) and biophysical stimuli (fluid shear stress) and thereby elucidate the active role of lymphatics in the regulation of tissue fluid drainage, inflammation, and pathophysiological conditions such as edema. Her work employed in vitro 3-D regenerative models of the tissue space, incorporating interstitial flow, to investigate gene regulation in lymphangiogenesis and angiogenesis and to define principles for the (re-)generation of vascularized engineered tissue. She was also actively involved in projects investigating the mechanisms of lymphogenous tumor cell metastasis and how the biophysical tumor microenvironment can influence this process.

Commissioner's Fellowship Project Overview

Evaluation of regenerative medicine devices that produce a biological product at the patient point-of-care: Assessment of device and output controls and enhancement of FDA review

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

Devices used at the patient "point-of-care" (POC) to process autologous biological material are becoming increasingly prevalent in the field of regenerative medicine. These devices are a prime example of emerging cell therapy-based technologies that pose both scientific and regulatory challenges in ensuring their safe use in the clinical setting. The challenges are in part attributed to complexities related to establishing device controls which may include parameters for device performance testing and additional characterization of the biological output, appropriate for a given intended use of the product. Therefore, this multi-center project aims to identify and define necessary controls for device and corresponding biological output to ensure that the quality of the output from such POC devices meets public health and regulatory needs. An anticipated outcome is a set of recommendations on science-based approaches to product development and regulatory review for certain POC devices relevant to regenerative cellular therapies.



Yueqin Zhao, Ph.D.

Center for Drug Evaluation and Research (CDER)

Preceptor: Ram Tiwari, Ph.D.

Scientific and Professional Background

2005-2010 Assistant Professor, Eastern Virginia Medical School, VA

2010 Ph.D. Computational and Applied Mathematics, Old Dominion University, VA

2005 M.S. Computational and Applied Mathematics, Old Dominion University, VA

2000 B.S. Statistics, Shanghai University of Finance and Economics, China

Research Interests

Signal Detection; Likelihood Ratio Test; Bayesian methods; Benefit Risk assessment.

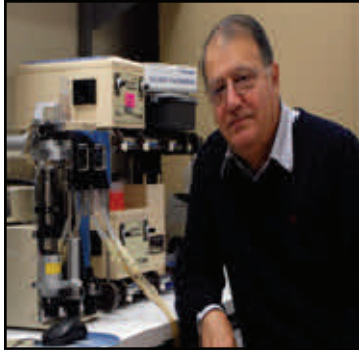
Commissioner's Fellowship Project Overview

Likelihood Ratio Test (LRT) for Safety Signal Detections in Clinical Trials

FDA Regulatory Science Priority Area: [Harness Diverse Data through Information Sciences to Improve Health Outcomes](#)

The likelihood ratio test (LRT), recently developed by Huang, Zalkikar and Tiwari (2011), for signal detection from large drug safety observational databases, such as Adverse Event Reporting System (AERS) database established by the U.S Food and Drug Administration is shown to control both the type-I error and false discover rate (FDR). An extension of LRT to Zero-Inflated Poisson (ZIP) model based LRT is also being developed by these authors, in order to model the extra zero counts in the large data matrix. Both the original LRT and ZIP model based LRT methods have been developed and applied to observational study databases. The goal of the project is to develop LRT tests for detecting the signals of AEs in clinical trial data environment.

FDA Commissioner's Fellowship Program
2012 Preceptors



Abdu I. Alayash, Ph.D.

Center for Biologics Evaluation and Research (CBER)
Laboratory of Biochemistry and Vascular Biology
Division of Hematology

Background

- Ph.D. (1978)
- DSc (2010)
- 23 years employment with FDA

Research Interests

Hemoglobin-based oxygen carriers (HBOCs) also known as “blood substitutes” are being developed to reduce the need for red blood cell transfusions in emergency trauma resuscitation, surgery and several other indications. Despite considerable advances in the design and manufacture of HBOCs, safety issues continue to slow the progress of this the field. Our laboratory has focused on the biochemical and physiological basis of oxidative toxicities and has established a direct link between the redox (reduction-oxidation) activity of HBOCs and their safety profiles *in vivo* and *in vivo*. Antioxidative as well as oxidative inactivation clearance interventions are being explored as possible protective strategies in controlling Hb oxidative side reactions



Ira Berkower, M.D., Ph.D.

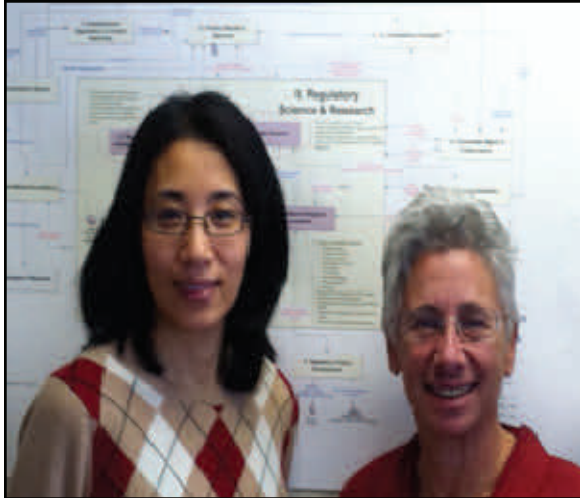
Center for Biologics Research and Evaluation (CBER)
Lab Chief, Lab of Immunoregulation
Division of Viral Products, Office of Vaccines

Background

Over the past 25 years, we have worked on regulating the products of biotechnology, including the first recombinant derived vaccine, the first monoclonal antibody in man, and peptide test kits for HIV. In the lab, we are using molecular immunology tools to understand and enhance the immune response to vaccine antigens. Two current approaches to enhance vaccine potency include: assembly of virus-like particle vaccines with or without attached cytokines, and protein expression by live attenuated viral vectors.

Research Interests

1. Virus-like particle vaccines for HIV, gp120 structure, cytokine enhanced vaccines.
2. Live attenuated viral vectors to deliver HIV antigens.



Li-Lun Chen, M.D.

Center for Tobacco Products (CTP)
Office of Science

Working in conjunction with:

Wendy Aaronson

Center for Tobacco Products (CTP)
Office of Science

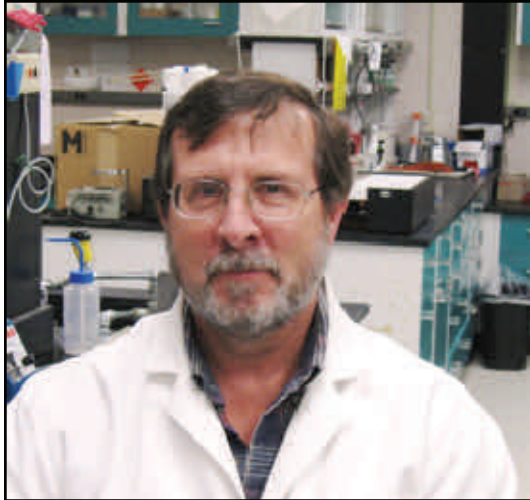
Background

Li-Lun Chen is a Clinical lead/Senior Medical Officer working with FDA for 4 years. Pediatrician and Assistant Clinical Professor of Pediatrics at George Washington School of Medicine.

Wendy Aaronson is Health Scientist and Director of the Regulatory Science Informatics Team. She has 33 yrs of FDA experience. MS in Microbiology from University of Maryland, College Park

Research Interests

(IC) Interested in health effects of new tobacco products such as hookahs and e-cigarettes.
(WA) Interested in coordinating, developing, and using standard terminology and data standards to improve data quality and facilitate regulatory decision-making.



Charles R. Clavet, M.S.

Office of Regulatory Affairs (ORA)
Winchester Engineering and Analytical Center
(WEAC) Winchester, MA

Background

- B.S. Microbiology, University of Rhode Island
- M.S. Microbiology, University of Rhode Island
- FDA experience - 20 years

Research Interests

My interest over the past 20 years has focused on regulatory issues in microbiology related to important public health concerns.



Vasily N. Dobrovolsky, Ph.D.

Division of Genetic and Molecular Toxicology
National Center for Toxicological Research (NCTR)

Background

- 1988 M.S., Biotechnology. Moscow Institute of Physics and Technology (Russia).
- 1994 Ph.D., Molecular Biology. Shemyakin Institute of Bioorganic Chemistry, Russian Academy of Sciences (Moscow, Russia).
- 1994 – 1998, Postdoctoral Fellow, Oak Ridge Institute for Science and Education (ORISE) (Oak Ridge, TN).
- FDA experience 15 years

Research Interests

Finding solutions to issues facing regulatory science using the most advanced technology and instrumentation. Developing and improving tools for assessment of safety and identification of potential hazards (i.e., carcinogens) in the products regulated by the U.S. FDA.

- In vivo and in vitro genetic toxicology
- Genetic engineering
- Transgenic technology
- High-throughput flow cytometry
- Regulatory science



Thomas Hammack, M.S.

Chief, Microbial Methods Development Branch
Division of Microbiology
Office of Regulatory Science
Center for Food Safety and Applied Nutrition (CFSAN)

Background

- M.S. Poultry Science. 1992 from The University of Maryland

Research Interests:

Development and validation of environmental testing methods for the detection of *L. monocytogenes* and *Cronobacter* in food processing environment



Saeed Khan, Ph.D.

Division of Microbiology
National Center for Toxicological Research (NCTR)

Background

- Ph.D.
- FDA Experience: 14 Yrs

Research Interests

Antimicrobial Resistance in bacteria, gene expression profiling, and anthrax disease biomarkers



John W. Larkin, Ph.D.

Center for Food Safety and Applied Nutrition (CFSAN)



Serguei Liachenko, M.D., Ph.D.

BioImaging Lab/Division of Neurotoxicology
National Center for Toxicological Research (NCTR)

Background

- M.D./Ph.D. in biochemistry/pharmacology (Russian State Medical University and National Center for Bioactive Compounds, Moscow, Russia)
- 7.5 years with Pfizer, Inc (Sr. Principal Scientist, Head of MRI)
- 2.5 years with FDA (Director of Bio-Imaging)

Mentorship Experience: 3 summer students, 1 graduate student, 3 postdoctoral fellows.

Research Interests

- Utilization of Magnetic Resonance Imaging and Spectroscopy (MRI/MRS) in preclinical study design.
- Imaging biomarkers of neurotoxicity
- Translational biomarkers of addiction
- Novel MRI/MRS data acquisition and analysis



Angel M. Paredes, Ph.D.

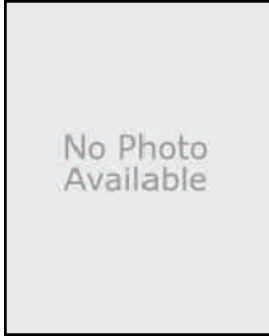
Director of Electron Microscopy Group, NCTR/ORA Nanotechnology Core Facility
Office of Scientific Coordination
National Center for Toxicological Research (NCTR)

Background

- Ph.D., Microbiology, University of Texas, 1993
- National Center for Molecular Imaging, Baylor College of Medicine, Houston, TX (1994-2004)
- Assistant Professor and Director High Resolution Cryo-Electron Microscopy Facility, Department of Pathology & Laboratory Medicine, University of Texas Health Sciences Center, Houston, TX (2005-2011)
- Director of Electron Microscopy Group, NCTR (2011-present)

Research Interests

Nanotechnology involves the study and manipulation of certain nano-scaled materials (~1-100 nm) for use in manufactured products. Some of these products include pharmaceuticals and medical devices, and from the FDA point of view, the potential adverse effect of these materials on human health is very important. For instance, many nanomaterials such as nano-silver, nano-gold, and nano-iron are being developed as drug delivery/organ targeting systems. My research goal is to use electron microscopy (EM) and computer aided 3D image reconstruction to investigate the structural basis of human cellular interaction with nanomaterials. As nanomaterials are introduced into a mammalian system, knowledge of the uptake, distribution, and disposition of the nanomaterial is critical for understanding potential benefit and risk. We will be using a state-of-the-art FEG Scanning Electron Microscope (SEM) with a novel new auto-ultramicrotome serial sectioning device (Gatan 3Veiw2) to look at the 3D structure of cells and organelles treated with nanomaterials. In particular, we are interested in the distribution of nanomaterial within the animal model and the effects these materials have at the cellular and organ level.



Eva Rorer, M.D.

Chief Ophthalmic Medical Officer
Division of Ophthalmic, Neurological and ENT Devices
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)

Background

Dr. Rorer ensures consistency of clinical reviews of ophthalmic devices across two branches of the Division and helps resolve complex and difficult issues involving ophthalmic device submissions. Dr. Rorer has extensive experience in ophthalmic device review and is recognized by the Center for her expertise as a clinical reviewer.



Debra Street, Ph.D., M.P.H.

Chief, Emergency Response & Surveillance Branch
Division of Public Health and Biostatistics
Center for Food Safety and Applied Nutrition (CFSAN)

Background

- Ph.D. - Epidemiology,
- M.P.H. - Epidemiology
- 17 years of FDA employment

Research Interests

- Improving characterization of adverse events reported by passive surveillance,
- Improving attribution methods for associating illness with specific foods,
- Chronic disease epidemiology



Ram C. Tiwari, Ph.D.

Associate Director, Office of Biostatistics

Center for Drug Evaluation and Research (CDER)

Background

- M.S. & Ph.D. (Mathematical Statistics), Florida State University
- Fellow, American Statistical Association
- Member, International Statistical Institute
- Previous Employment: Mathematical Statistician and Program Director, Surveillance Research program, NCI/NIH (2000-2008);
- Professor & Chairman, Department of Mathematics, University of North Carolina, Charlotte, NC (1994-2000);
- Asst./Assoc./Professor, Department of Mathematics, University of North Carolina, Charlotte, NC (1986-1994);
- Asst. Professor, Indian Institute of Technology, Bombay (2002-2006); Visiting Lecturer, UC Santa Barbara (1981-1982, 1985-1986).

Research Interests

Development of statistical methods for i) clinical trials; and ii) signal detection in drug safety surveillance.



Donna Williams-Hill, Ph.D.

Office of Regulatory Affairs (ORA)
Pacific Regional Laboratory Southwest

Background

- 1975, B.S. Biology, magna cum laude, Chemistry Minor Northern Illinois University, DeKalb,
- 1980, M.S. Biology, Illinois Institute of Technology, Chicago, IL.
- 1992, Ph.D. Microbiology, University of Southern California, Los Angeles, CA.
- 1992-1995, Post-doctoral Fellow Department of Human Oncology, University of Wisconsin, Madison, WI.
- FDA Employee: 12/31/2000

Research Interests

Projects center on development of molecular methods to detect pathogens in foods:

1. Detection of high risk pathogens (select agents) including *Bacillus anthracis*, *Yersinia pestis* and *Francisella tularensis* using BSL-3 safety procedures;
2. Assessing emerging technologies for the rapid detection of bacterial and viral pathogens
- 3..Improving current cultural enrichment techniques to enhance the detection of target bacterial pathogens in foods.



Lei Zhang, Ph.D.

Special Assistant to Office Director
Immediate Office
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER)

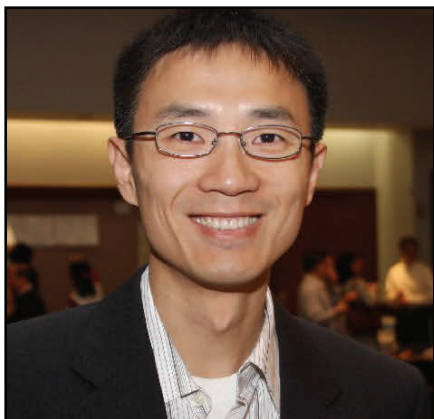
Background

- Ph.D. in Biopharmaceutical Sciences, University of California, San Francisco
- Pharmaceutical Industry Experience – 4 years
- FDA Experience – 11 years

Research Interests

My research interests include role of transporters in drug interactions, pharmacogenomics of metabolizing enzymes and transporters, interplay of drug metabolizing enzymes and transporters, effect of renal or hepatic impairment on enzymes and transporters, and pharmacokinetics/pharmacodynamics.

Membrane transporters represent ~15% of the human genome of approximately 30K genes. These transporters are expressed in many tissues such as the intestine, liver, kidney and brain, and play key roles in drug absorption, distribution and excretion. As such, transporters can affect the pharmacokinetics and pharmacodynamics of a drug whether acting alone or in concert with drug metabolizing enzymes. Increasing number of examples in the literature and regulatory reviews have demonstrated that drug interactions and polymorphisms involving transporters can affect safety or efficacy of therapeutics, e.g., organic cation transporting polypeptides (OATPs) and cholesterol lowering statin drugs. Transporters represent an emerging area for regulatory research. I lead a Transporter Scientific Interest Group (SIG) in the Office of Clinical Pharmacology/Office of Translational Sciences to conduct regulatory research projects in the transporter area and we have generated data to support regulatory guidance development, e.g., FDA's recently published draft drug interaction guidance (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM292362.pdf>, February 2012).



Ping Zhao, Ph.D.

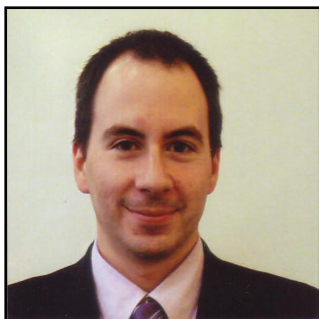
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research (CDER)

Background

- Ph.D. – Drug Metabolism and Pharmacokinetics
- Pharmaceutical industry experience – 6 years
- FDA Experience – 3.5 years

Research Interests

Use of population-based, physiologically-based pharmacokinetic (PBPK) modeling and simulations to facilitate regulatory review of clinical pharmacology issues.



Kenneth J. Cavanaugh Jr., Ph.D.

Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
Division of Cardiovascular Devices

Background

- Bachelor of Chemical Engineering with Minors in Chemistry and Biology, Villanova University
- Ph.D. in Bioengineering, University of Pennsylvania
- FDA experience – 8 years

Research Interests

Dr. Cavanaugh is the Chief of the Peripheral Vascular Devices Branch (PVDB), Division of Cardiovascular Devices (DCD), Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), a position he has held since 2008. PVDB is responsible for the pre-market review of all cardiovascular devices used outside the heart and brain, including vascular stents, vascular and endovascular grafts, inferior vena cava filters, and angioplasty catheters. Many of these devices incorporate biologic components (e.g. vascular grafts involving protein coatings or originating from animal tissue) or are combination products involving substantial device and drug components (e.g. drug-eluting stents or drug-coated angioplasty balloons).

From 2003 to 2008, Dr. Cavanaugh was a biomedical engineer and scientific reviewer in PVDB, focusing on the review of carotid and renal artery stents and embolic protection devices, combination products, and delivery systems for cell and gene therapies. He holds a bachelor's degree in chemical engineering with minors in biology and chemistry, and a Ph.D. in bioengineering. His dissertational research focused on lung injury mechanics.



Charles N. Durfor, Ph.D.

Expert Reviewer
Division of Surgical, Orthopedic and Restorative Devices
Office of Device Evaluation (ODE)
Center for Devices and Radiological Health (CDRH)

Background

- B.S. (Chemistry) College of William and Mary
- Ph.D. (Bioorganic Chemistry) University of Virginia

Research Interests

Dr. Durfor is an expert regulatory reviewer in the Plastic and Reconstructive Surgery Devices Branch (PRSB), Division of Surgical, Orthopedic and Restorative Devices (DSORD), Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH). Dr. Durfor has served in the Plastic and Reconstructive Surgery Devices Branch of ODE since June 26, 1994. Previously, he was employed, (since November 8, 1988), by the Center for Biologics Evaluation and Research (CBER) and the National Institutes of Health (NIH) within the Public Health Service (PHS). He was also the lead reviewer for the first cellular device products to receive PMA (Apligraf) and HDE (OrCel) approvals.

PRSB reviews 510(k)s, IDEs, HDEs and PMAs seeking approval for devices for: wound healing (e.g., acute burn wounds and chronic ulcers) and soft tissue repair (e.g., facial, peritoneal and lung tissues) as well as several biological and drug products containing device materials through InterCenter consults. Many of these devices contain components composed of physiological materials (e.g., cells, proteins and polysaccharides) or biosynthetic (e.g., *in situ* crosslinking or polymerizing) materials. Dr. Durfor's experience includes regulation of mammalian cell culture products and *in situ* polymerizing medical devices, research on protein structure/function, and considerable exposure to clinical trial design issues (e.g., from 200-2001 he served as the Chairman of the InterCenter Clinical Wound Healing Group). He is currently the CDRH expert on "the chemistry and manufacturing of biosynthetic, cellular and tissue-derived medical devices for soft tissue repair."



Steven S. Oh, Ph.D.

Team Lead, Device and Combination Product
Division of Cellular and Gene Therapies
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research (CBER)

Background

- Ph.D., University of Michigan
- Postdoctoral Fellowship, Johns Hopkins University School of Medicine and Massachusetts Institute of Technology
- Faculty, Tufts University School of Medicine
- FDA Experience – Since 2007

Research Interests

Dr. Oh serves as Team Lead for device evaluation in the Division of Cellular and Gene Therapies. His areas of regulatory expertise include device-biologic combination products, tissue engineered products, and medical devices with regenerative or therapeutic indications. He provides leadership in reaching various regulatory decisions on products submitted for marketing, clinical investigation, or classification. He also actively participates in policy development and staff training for these combination products as well as devices that produce biologic as the output. Dr. Oh spent some time in CDRH serving as a visiting review scientist from CBER. This unique experience has been crucial to Dr. Oh's understanding and appreciation of balanced approaches to biologic and device regulation. Upon returning to CBER from CDRH, Dr. Oh has founded Device Biologics Interest Group (DBIG) in 2008 providing a forum to regulatory staff in CBER and CDRH to learn and exchange ideas about regulations, policies, standards, technologies, and review practices applicable to devices and device-biologic combination products. He continues in the effort to harmonize scientific review practices and standards for combination products and devices regulated by CBER and CDRH.